

**AMENDMENT TO THE AMENDMENT IN THE
NATURE OF A SUBSTITUTE TO H.R. 7667
OFFERED BY MR. CARTER OF GEORGIA**

Page 93, strike lines 8 through 24 and insert the following:

1 “(H)(i) Upon request (in controlled correspond-
2 ence or otherwise) by a person that has submitted
3 or intends to submit an abbreviated application
4 under this subsection for a new drug that is re-
5 quested, under section 314.94(a)(9) of title 21, Code
6 of Federal Regulations (or a successor regulation),
7 to be qualitatively and quantitatively the same as the
8 listed drug with respect to inactive ingredients, or on
9 the Secretary’s own initiative during the review of
10 such an abbreviated application, the Secretary shall
11 inform the person whether such new drug is quali-
12 tatively and quantitatively the same as the listed
13 drug.

14 “(ii) If, pursuant to clause (i), the Secretary de-
15 termines that such new drug is not qualitatively or
16 quantitatively the same as the listed drug, the Sec-
17 retary shall identify and disclose to the person—

1 “(I) the ingredient or ingredients that
2 cause the new drug not to be qualitatively or
3 quantitatively the same as the listed drug; and

4 “(II) whether the quantity or proportion of
5 any ingredient in the new drug is greater than
6 or less than the quantity or proportion of that
7 ingredient in the listed drug.

